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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,517	10/31/2003	Dale B. Schenk	015270-0089.20US	8113
20350 7590 05/13/2008 TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834				
EXAMINER STANDLEY, STEVEN H				
ART UNIT		PAPER NUMBER		
1649				
MAIL DATE		DELIVERY MODE		
05/13/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/699,517

Applicant(s)

SCHENK ET AL.

Examiner

STEVEN H. STANDLEY

Art Unit

1649

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-46, 48, 50-55, 71-76 and 78-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-46, 48, 50-55, 71-76 and 78-84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Detailed Action

Response to Amendment

The amendment filed 1/22/07 has been made of record.

Claims 41-46, 48, 50-55, 71-76, and 78-84 are under examination.

Objections/Rejections: Maintained/New Grounds

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Rejection of claims 41-46, 48, and 50-55 and 71-76, and 78-80 under 35 USC § 112, 1st paragraph, enablement is maintained for the reasons made of record in the office actions dated 10/07/05 and 5/15/06 and 6/06/07. Claims 41-46, 48, and 50-55 are still rejected to the extent that 'therapeutically treating' includes prophylactically treating. Applicant's arguments have been fully considered and not found to be persuasive. The definition of therapeutically treating that applicant has provided in the specification (page 45, [0137]) includes administration to patients *suspected of*, or already suffering from the disease and to *prophylactically treating*. Applicant argues on page 6 of Remarks dated 12/06/07 that claims are limited to "patients suffering" from the disease. This is not found persuasive because Parkinson's disease often results in the loss of the majority of dopaminergic neurons in the striatum before any signs, symptoms, or diagnostics indicate the patient is (and has been) suffering from the

disease, however it is clear that having lost all those neurons the patient was suffering long before symptom or diagnosis. Thus, applicant is treating unknown and undiagnosed Parkinson's.

Applicant also argues on page 6 of Remarks that "With respect to claims 71-76 and 78-80, which are directed to prophylactic treatment, the office action incorrectly states that claims are directed to treating persons with no signs, symptoms or risks for Parkinson's disease. To the contrary, the claims specify that the patient has a known genetic risk of Parkinson's disease. Therefore, most of the office action's comments directed to alleged difficulties of prophylaxis of patients not having a known genetic risk of Parkinson's disease are not relevant to the claims now pending." This is not found persuasive because applicant is attributing an argument made by the examiner about claims 41 and 48 to claims 71-76 and 78-80. See the top of page 3 in the prior action of 6/07. Claims 71-76 and 78-80 are directed *exclusively at prophylactically treating*.

Because the Examiner interprets the treatable patient population in claims 41-46, 48, and 50-55 to include patients free of disease signs, or symptoms, and because claims 71-76 and 78-80 exclusively relate to prophylactically treating (patients with a known genetic risk), the claims remain rejected as not enabled for reasons made of record in the actions of 4/07/05, 9/30/05, 10/07/05, 5/15/06, and 6/06/07.

The prior art establishes several factors that indicate the invention does not work. Firstly, the animal model used to enable the treatment of PD herein does not include animals "at risk of," or "at genetic risk for" the disease because all animals get it, or they don't get it at all. Thus, the animal model is not a model population "at risk for," but one

that will absolutely get it. Clearly, any genetic risk is not an absolute determinant and therefore applicant has no idea if the instant treatment works in such cases. Prophylaxis cannot be tested because all animals in the animal model are destined to get the disease or not. The transgenic animals used all develop symptoms of PD such as Lewy body deposits and neuropathology and therefore do not enable treatment of a patient 'at risk for PD.' Furthermore, much evidence suggests that environmental factors such as toxins play a key role in initiating PD. Therefore as argued in the prior office action, the animal model does not take into account any other effects but the ones caused by the transgenic animal expressing mutant human synuclein. Therefore it cannot treat a patient 'at risk' for PD. Also, patient's having a known genetic risk do not always get PD, as does the animal model. Therefore the animal model is not appropriate for assessing a population at "genetic risk."

The specification lacks any enabling disclosure by way of instruction or example of prophylactic treatment. There are no animals treated that are 'at risk of' getting PD.

Therefore given the complexity of the invention, the contrasting prior art, and the lack of any teaching or example in the specification, it would require undue experimentation for one of skill in the art would to know how to use the invention as claimed.

Claim Rejections - 35 USC § 102

Rejection of claims 41, 42, 44, 45, 46, 48, 50, 51-55, 71, 72 74, 75 and 76, and 80-84 under 35 USC § 102(e) over Jensen is maintained for the reasons made of record in the office action dated 10/07/05. Applicant's arguments have been fully

considered and not found to be persuasive. See the Examiner's arguments in the previous office actions of 10/07/05 and 5/15/06, and 6/06/07.

Claim Rejections - 35 USC § 103

Rejection of claims 41, 43-46, 48, 50-55, 71, 73-76, 78-80 and 80-84 under 35 USC § 103(a) is maintained for the reasons made of record in the office action dated 10/07/06. Applicant's arguments have been fully considered and not found to be persuasive. Applicant's arguments have been fully considered and not found to be persuasive. See the Examiner's arguments in the previous office actions of 10/07/05 and 5/15/06 and 6/06/07.

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on **(571) 272-0911**.

The fax number for the organization where this application or proceeding is assigned is **(571) 273-8300**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

Art Unit: 1649

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.

5/07/08

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649